

**REMARKS**

This Amendment is submitted as a full and complete response to the Second and Final Office Action dated March 12, 2003. By this Amendment, applicants have further cancelled Claims 3, 4, 8, and 9 without prejudice and have amended again 1 and 7. Accordingly, it is now believed that amended independent Claims 1 and 7 and the remaining claims dependent thereon have been placed in condition for allowance.

In this Second and Final Office Action, it is noted that the Examiner has rejected Claims 1, 3, 7-9, 11-14 and 16 under 35 U.S.C. 102 as being allegedly anticipated by Phillips, U.S. Patent No. 5,840,737, taken in view of The Merck Index (1983). The Examiner has stated that the '737 patent discloses benzimidazole solution/suspension formulations comprising sodium bicarbonate where a suspension formulation is administered to a patient who is unable or unwilling to swallow tablets or capsules with an artificial feeding tube such as a nasogastric tube. He has expressed that the amount of sodium bicarbonate in the formulation is taught to be within the range of the present invention. While the Examiner admits that the '737 patent does not specifically give the pH

of the solution/suspension, he has indicated that this is an inherent property of sodium bicarbonate as set forth by in The Merck Index, page 8408. However, applicants respectfully disagree with the Examiner in these contentions.

Nevertheless, and in an effort to better distinguish the instant invention over the cited prior art, applicants have now cancelled Claims 3 and 4 and have incorporated the subject matter thereof into amended independent Claims 1. Similarly, applicants have cancelled Claims 8 and 9 and have incorporated the subject matter thereof into amended independent Claim 7. It is submitted that none of the prior art references can, singly or in any combination be deemed to anticipate or make obvious all of the new and novel features as now recited with particularity in amended independent Claims 1 and 7.

In particular, independent Claim 1 has been amended so as to recite the method for the formulation and delivery of an acid-labile pharmaceutical compound in which the basic salt has the limitation as being one of magnesium, calcium and aluminum. Independent Claim 7 has likewise been amended to recite an acid-labile pharmaceutical compound that in which the basic salt has the limitation as being one of magnesium,

calcium and aluminum.

The '737 patent to Phillips merely discloses a method for treating gastric acid disorders by administering to a patient a single dose of a pharmaceutical composition in a pharmaceutically acceptable carrier consisting essentially of a bicarbonate salt of a Group IA metal. This means that only sodium bicarbonate ( $\text{NaHCO}_3$ ) is usable since the remaining Group IA metal (i.e., Li, K) are neither safe nor appropriate for human administration in this manner. However, sodium salts including sodium bicarbonate are contraindicated in patients with hypertension (high blood pressure), heart disease including heart failure, kidney disease, liver disease, and pulmonary edema. Since most of the patients who require suspensions are elderly and commonly have one of these above-listed conditions or illnesses, sodium bicarbonate-based formulations would not be a medically suitable option for them.

On the other hand, in the present invention the basic salt is one of magnesium, calcium and aluminum which is used to provide a carrier for the pharmaceutical compound. When calcium is used, it has the advantage of having no obvious

contraindications and is usable by all patients. Further, since calcium is recommended as a supplement for post-menopausal women and older men so as to prevent osteoporosis, calcium carbonate-based formulations will be more appropriate for these patients. Moreover, calcium may serve to reduce recurrence of colon polyps and, potentially, the incidence of colon cancer. In addition, calcium stimulates the release of gastrin, which in turn stimulates acid production from gastric parietal (acid-secreting) cells. Parietal cell activation is required for the action of the pharmaceutical compound. Thus, by using calcium to potentiate the effect of the pharmaceutical compound on the parietal cells, better acid suppression will be achieved.

Clearly, neither the '737 patent nor the Merck Index teach or suggest an acid-labile pharmaceutical compound using a basic salt of one magnesium, calcium and aluminum as the carrier. It is submitted that the '737 patent and the Merck Index do not, in any way, anticipate or make obvious the present invention as recited with particularity in amended Claims 1 and 7. Therefore, it is believed that amended independent Claims 1 and 7 of the present invention are clearly distinguishable over the prior art of record and are

thus in condition for allowance.

In view of the foregoing amendments advanced to the claims, it is now believed that amended independent Claims 1 and 7 and the remaining claims dependent thereon have been placed in condition for allowance. Therefore, a formal Notice of Allowance is believed to be in order and the same is earnestly solicited.

Alternatively, should the Examiner not permit the allowance of this case, then entry of this Amendment is solicited on the grounds that the application will be placed in better form for an Appeal.

In the event the Examiner is of the opinion that the prosecution of this application may be expedited by direct contact with applicants' attorney, he is requested to call Davis Chin at (708)403-9688, Orland Hills, Illinois.

Respectfully submitted,

BY: 

DAVIS CHIN  
Registration No. 26,854  
16061 S. 94th Avenue  
Orland Hills, IL 60477  
(708) 403-9688

Attorney for Applicants

DC/d  
00B-2027